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PTO-1390 (Rev. 07-2005) Approved for use through 3/31/2007. OMB 0651-0021

U.S. Pathing Delegation
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## TRANSMITTAL LETTER TO THE UNITED STATES **DESIGNATED/ELECTED OFFICE (DO/EO/US)** CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER 3024-114

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

| TERMAT          | TIONAL | APPL  | ICATI | ON | NO |
|-----------------|--------|-------|-------|----|----|
| <b>=</b> 0/₩//s | -0200  | 4/00F | 212   |    |    |

INTERNATIONAL FILING DATE

PRIORITY DATE CLAIMED

| PQT/E   | EP2004/005213   | May 14, 2004                                   | May 14, 2003                                     |  |  |
|---|---|--|--|--|--|
| LE OF,  | ELE OF, INVENTION  The of-several enzyme-containing compositions, dietetic food products and medicaments produced therefrom, and their use for medical purposes |  |  |  |  |
| ALPLICAN  | APPLICANT(S) FOR DO/EO/US  Winfried Miller  |  |  |  |  |
| Applicant   | herewith submits to the United Sta  | ites Designated/Elected Office (DO/EC          | D/US) the following items and other information: |  |  |
| 1. 🛛 1  | 1. X This is a FIRST submission of items concerning a submission under 35 U.S.C. 371.   |  |  |  |  |
| 2. T  | his is a SECOND or SUBSEQUENT s   | ubmission of items concerning a submission     | n under 35 U.S.C. 371.                           |  |  |
| з. 🔀 т  | This is an express request to begin nati<br>(5), (6), (9) and (21) indicated below.   | onal examination procedures (35 U.S.C. 37      | 1(f)). The submission must include items         |  |  |
| 4. 🔲 1  | The US has been elected (Article 31).   |  |  |  |  |
| 5.  | A copy of the International Application as filed (35 U.S.C. 371(c)(2))  |  |  |  |  |
|   | a. is attached hereto (required   | only if not communicated by the internation    | nai Bureau).                                     |  |  |
|   | b. As been communicated by  | the International Bureau.                      |  |  |  |
|   | c. is not required, as the applic   | cation was filed in the United States Receivi  | ing Office (RO/US).                              |  |  |
| 6. 🗵  | An English language translation of the  | e International Application as filed (35 U.S.C | C. 371(c)(2)).                                   |  |  |
|   | a. is attached hereto.  |  |  |  |  |
|   | b. has been previously submit   | tted under 35 U.S.C. 154(d)(4).                |  |  |  |
| 7.  | Amendments to the claims of the Inte  | rnational Application under PCT Article 19 (   | (35 U.S.C. 371(c)(3))                            |  |  |
|   | a. are attached hereto (required only if not communicated by the International Bureau).   |  |  |  |  |
|   | b. have been communicated by the International Bureau.  |  |  |  |  |
|   | c. have not been made; however, the time limit for making such amendments has NOT expired.  |  |  |  |  |
| Ē   | d. have not been made and will not be made.   |  |  |  |  |
| 8. 🗆  | An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).   |  |  |  |  |
| 9. 🗵  | An oath or declaration of the inventor  | (s) (35 U.S.C. 371(c)(4)).                     |  |  |  |
| 10.   | An English language translation of the Article 36 (35 U.S.C. 371(c)(5)).  | e annexes of the International Preliminary E   | Examination Report under PCT                     |  |  |
| Items 11 to 20 below concern document(s) or information included: |   |  |  |  |  |
| 11. 🗵   | An Information Disclosure Statement   | under 37 CFR 1.97 and 1.98.                    |  |  |  |
| 12. 🔀   | An assignment document for recording  | ng. A separate cover sheet in compliance w     | ith 37 CFR 3.28 and 3.31 is included.            |  |  |
| 13. 🗵   | A preliminary amendment.  |  |  |  |  |
| 14.   | An Application Data Sheet under 37 CFR 1.76.  |  |  |  |  |
| 15. 🗆   | A substitute specification.   |  |  |  |  |
| 16. 🗵   | A power of attorney and/or change of address letter.  |  |  |  |  |
| 17.   | A computer-readable form of the seq   | uence listing in accordance with PCT Rule      | 13ter.2 and 37 CFR 1.821- 1.825.                 |  |  |
| 18. 🗵   | A second copy of the published International Application under 35 U.S.C. 154(d)(4).   |  |  |  |  |
| 19.   | A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).   |  |  |  |  |

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S.

JC06 Rec'd PCT/PT0 31 OCT 2005

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U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

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| U.S. APPLIQA   | ION NO (if known,   | see 37 GFR 1.5)   | INTERNATIONAL APP   | LICATION NO.                               | ATTORNEY'S D           | OCKET NUMBER       |
|--|---|---|---|--|------------------------|--------------------|
| U.S. APPLICATION NO. (II, Known See 37 GFR 1.5)  INTERNATIONAL APPLICATION NO. PCT/EP2004/005213   |   | 3024-114  |   |  |                        |                    |
| 20. Other items or information:  |   |   |   |  |                        |                    |
| The follo  | owing fees have b   | een submitted   |   |  | CALCULATIONS           | PTO USE ONLY       |
|  | =   |   |   | \$300                                      | \$ 300.00              |                    |
| 22. 🔀 Exam   | nination fee (37 CF   | R 1.492(c))   | ***   |  |                        |                    |
| If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)\$0  All other situations\$200 |   |   |   | \$ 200.00                                  |                        |                    |
| If the written opin<br>IPEA/US<br>Search fee (37 C<br>International Sea<br>previously  | indicates all claim<br>FR 1.445(a)(2)) had<br>onal Searching Aut<br>rch Report prepare<br>communicated to | or the Internation as satisfy provision as been paid on the thorityed by an ISA othe the US by the IB | nal preliminary examination reprins of PCT Article 33(1)-(4) he international application to the than the US and provided to 3    | \$0 he USPTO as an\$100 the Office or\$400 | \$ 400.00              |                    |
| ·  | TOTAL OF 21, 22   | 2 and 23 =  | <del></del>   |  | \$1000.00              |                    |
| Additional fe sequence electronic  | e for specification<br>e listing in complia<br>c medium) (37 CF   | and drawings file<br>nce with 37 CFR<br>R 1.492(j)).<br>Iditional 50 sheet                            | d in paper over 100 sheets (ex<br>1.821(c) or (e) or computer pro<br>s of paper or fraction thereof.<br>additional 50 or fraction | cluding<br>ogram listing in an<br>RATE     |                        |                    |
| Total officeto   |   |   | thereof (round up to a whole number)  |  |                        |                    |
| - 100 =  | /50 =   |   |   | x \$250                                    | \$                     |                    |
| Surcharge of \$13 after the date of  | 80.00 for furnishing commencement of  | any of the searce<br>the national stag  | ch fee, examination fee, or the oge (37 CFR 1.492(h)).  | oath or declaration                        | \$                     |                    |
| CLAIMS   | NUMB  | ER FILED  | NUMBER EXTRA  | RATE                                       | \$                     |                    |
| Total claims   | 29  | - 20 =  | 9   | x \$ 50                                    | \$ 450.00              |                    |
| Independent clai   | ms 1  | - 3 =   | 0   | x \$200                                    | \$                     |                    |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$360  |   |   | \$  |  |                        |                    |
|  |   |   | TOTAL OF ABOVE  |  | \$                     |                    |
| Applicant cla  | ims small entity st   | atus. See 37 CF   | R 1.27. Fees above are reduce   | ed by 1/2.                                 |                        |                    |
| _  |   |   |   | SUBTOTAL =                                 | \$ 1450.00             |                    |
| _  | f <b>\$130.00</b> for furni<br>late (37 CFR 1.49  | -   | translation later than 30 month   | s from the earliest<br>+                   | \$                     |                    |
|  |   |   | TOTAL   | NATIONAL FEE =                             | \$ 1450.00             |                    |
| Fee for recording by an appropriate  | the enclosed ass<br>e cover sheet (37   | ignment (37 CFF<br>CFR 3.28, 3.31).   | t 1.21(h)). The assignment mus<br>\$40.00 per property  | t be accompanied<br>+                      | \$ 40.00 (depos        | sit account auth.) |
|  |   |   | TOTAL FE  | EES ENCLOSED =                             | \$ 1450.00             |                    |
|  |   |   |   |  | Amount to be refunded: | \$                 |
|  |   |   |   |  | Amount to be charged   | \$                 |

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| a. A check in the amount of \$ 1450.00 to cover the above  | 0/555244<br>Tees is enclosed.                               |  |  |  |
|--|---|--|--|--|
| b. Please charge my Deposit Account No in the amount of \$ _ A duplicate copy of this sheet is enclosed.   | to cover the above fees.                                    |  |  |  |
| c. The Commissioner is hereby authorized to charge any additional fees which Account No. 50-3135. A duplicate copy of this sheet is enclosed.  | h may be required, or credit any overpayment to Deposit     |  |  |  |
| d. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. |   |  |  |  |
| NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a and granted to restore the International Application to pending status.   | a petition to revive (37 CFR 1.137(a) or (b)) must be filed |  |  |  |
|  |   |  |  |  |
| SEND ALL CORRESPONDENCE TO:  | Jace V. Wikus   |  |  |  |
| Customer No. 46002   | Joyce von Natzmer   |  |  |  |
| Att. Joyce von Natzmer<br>4615 North Park Avenue   | NAME  |  |  |  |
| Suite 919  | 48,120  |  |  |  |
| Chevy Chase, MD 20815  | REGISTRATION NUMBER   |  |  |  |
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|                                       | Attorney Docket No.  | 3024-116                           |  |
|---------------------------------------|--|------------------------------------|--|
| <b>New Utility Patent Application</b> | Appl. No.  | Nat. Stage of<br>PCT/EP2004/005213 |  |
|                                       | Group  | NA                                 |  |
|                                       | First Inventor   | Miller                             |  |
|                                       | Title One or several enzyme-containing compositions, dietetic food products and medicaments produced therefrom, and their use for medical purposes |                                    |  |

## CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10

(When using Express Mail, the Express Mail label number is **mandatory**; Express Mail certification is optional.)

I hereby certify that, on the date shown below:

- Form PTO-1390 (3 pgs);
- Translation of PCT/EP2004/005213 including verification (31 pgs);
- Application data sheet (2pgs);
- Inventor's declaration incl. power (2pgs);
- preliminary amendment (10 pgs);
- Information Disclosure Statement (2 pgs) incl. Form 1449 (2 pgs);
- International search resport for PCT/EP2004/005213 (10 pgs);
- GB1390542 and literature article (see 1449);
- assignment including recordation sheet (2pgs);
- Extra copy of WO 2004/100981; and
- JvN check #1158 for \$1450.00 & return postcard.

are being deposited for the subject application with the United States Postal Service in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

□ 37 C.F.R. § 1.8(a)

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10√37 C.F.R. § 1.10

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Joyce von Natzmer

(type or print name of person certifying)

10/555244 JC06 Rec'd PCT/PTO 31 OCT 2005

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:

U.S. National Serial No.:

Filed:

PCT International Application No.:

PCT/EP2004/005213

## **VERIFICATION OF A TRANSLATION**

I, Susan ANTHONY BA, ACIS,

Director of RWS Group Ltd, of Europa House, Marsham Way, Gerrards Cross, Buckinghamshire, England declare:

That the translator responsible for the attached translation is knowledgeable in the German language in which the below identified international application was filed, and that, to the best of RWS Group Ltd knowledge and belief, the English translation of the international application No. PCT/EP2004/005213 is a true and complete translation of the above identified international application as filed.

I hereby declare that all the statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the patent application issued thereon.

Date: October 7, 2005

Signature:

For and on behalf of RWS Group Ltd

Post Office Address:

Europa House, Marsham Way,

Gerrards Cross, Buckinghamshire,

England.